REMARKS

Upon entry of the foregoing amendment, claims 1, 3, 4, 6, 7 and 9-52 are pending in this patent application with claims 1, 4, 7, 10, 14, 17, 21, 25, 29, 32, 37, 43, and 46 being the independent claims.

Rejections Under 35 U.S.C. 103(a)

Claims 1, 3, 4, 6, 7, and 9-15, 16-35, and 37-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 2003-12708 to Doi ("Doi") in view of U.S. Patent No. 6,030,554 to Ichihara ("Ichihara"). The Examiner asserts that Doi teaches all of the features of the rejected claims except "a separate container for the articles, which container holds the articles and wherein the two regulators are disposed external to the container."

Doi discloses an irradiation system that includes a source of electron beams and a dose adjuster (10). In an embodiment, the dose adjuster (10) includes two halves that combine to form cavities that are shaped to complement the shape of the articles to be irradiated. Prior to irradiation, an individual article must be placed into each cavity. The combined articles and halves are then irradiated.

Ichihara discloses a method of sterilizing an intraocular lens using an electron beam. The method includes sealing an intraocular lens in a sealed container and irradiating the intraocular lens. The sealed container is configured to allow the transmission of the electron beam while prohibiting the ingress of microorganisms.

Those references fail to disclose or suggest all of the features recited in independent claims 1, 4, 7, 10, 14, 17, 21, 25, 29, 32, 37, 43 and 46. All of the independent claims recite a closed container that is configured to house a plurality of articles in a predetermined

configuration and a radiation absorbing fixture that is coupled externally to the closed container. As described above, Doi teaches a radiation dose adjuster that may be configured to receive individual articles and the Examiner recognized that Doi fails to disclose attaching the dose adjuster externally to a container that holds the articles.

Ichihara does not remedy the failure of Doi because Ichihara also fails to disclose attaching a dose adjuster externally to a container that holds the articles. Ichihara simply discloses sealing an intraocular lens in a gas-tight container prior to irradiation. Ichihara does not suggest using a dose adjuster external to a bulk container because such features would be unnecessary and undesirable for sterilizing intraocular lenses. First, intraocular lenses are thin devices that would not require a dose adjuster to compensate for their thickness. Additionally, intraocular lenses would not be packaged in bulk because a bulk quantity of lenses would not be necessary for any patient. As a result, the references either alone or in combination fail to disclose all of the features recited in the independent claims.

Housing a plurality of articles in a closed container in a predetermined configuration and utilizing an external radiation absorbing fixture provides significant advantages not recognized by the cited references. In particular, housing the plurality of articles in a closed container prior to irradiation minimizes the handling of the articles because only the bulk container would be directly handled after the initial packaging. In addition, the dose adjuster of Doi includes irregularities as a result of the cavities shaped therein. The insertion and removal of articles within those cavities create wear on the irregularities which could change the characteristics of the dose adjuster over time. In the present invention, the fixture is attached externally of the closed container so any irregularities in the fixture need not be subjected to repetitive wear.

Therefore, claims 1, 4, 7, 10, 14, 17, 21, 25, 29, 32, 37, 43 and 46 are each patentable over Doi in combination with Ichihara. Claim 3 depends from and includes all of the features of claim 1 and for the same reasons is patentable over Doi and Ichihara. Claim 6 depends from and includes all of the features of claim 4 and for the same reasons is patentable over Doi and Ichihara. Claim 9 depends from and includes all of the features of claim 7 and for the same reasons is patentable over Doi and Ichihara. Claims 11-13 depend from and include all of the features of claim 10 and for at least the same reasons are patentable over Doi and Ichihara. Claims 15 and 16 depend from and include all of the features of claim 14 and for at least the same reasons are patentable over Doi and Ichihara. Claims 18-20 depend from and include all of the features of claim 17 and for at least the same reasons are patentable over Doi and Ichihara. Claims 22-24 depend from and include all of the features of claim 21 and for at least the same reasons are patentable over Doi and Ichihara. Claims 26-28 depend from and include all of the features of claim 25 and for at least the same reasons are patentable over Doi and Ichihara. Claims 30 and 31 depend from and include all of the features of claim 29 and for at least the same reasons are patentable over Doi and Ichihara. Claims 33 and 34 depend from and include all of the features of claim 32 and for at least the same reasons are patentable over Doi and Ichihara. Claims 38-42 depend from and include all of the features of claim 37 and for at least the same reasons are patentable over Doi and Ichihara. Claims 44 and 45 depend from and include all of the features of claim 43 and for at least the same reasons are patentable over Doi and Ichihara. Claims 47-52 depend from and include all of the features of claim 46 and for at least the same reasons are patentable over Doi and Ichihara.

Claims 16 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doi in view of Ichihara as applied to claims 15 and 32 above, and further in view of U.S. Patent No.

5,590,602 to Peck et al. ("Peck"). The Examiner relies upon Peck for teaching "spacing containers and fixtures by a particular distance when being moved past the radiation source."

Peck discloses a conveyor system that includes a plurality of article carriers, a process conveyor, an overhead power and free transport conveyor, and a load conveyor. The process conveyor supports article carriers and transports them past a radiation source at a second speed.

Similar to Doi and Ichihara, Peck neither alone nor in combination with those references discloses all of the features recited in independent claims 14 and 32, from which claims 16 and 36 depend. In particular, Peck does not disclose a fixture coupled externally to the article containers that may be used to adjust the radiation at different locations in the articles. As a result, Peck does not remedy the failure of Doi and Ichihara to disclose all of the recited features of claims 14 and 32. Therefore, claims 14 and 32 are patentable over a combination of Doi, Ichihara and Peck. Claim 16 depends from and includes all of the features recited in claim 14 and for at least the same reasons is patentable over Doi, Ichihara and Peck. Claim 36 depends from and includes all of the features recited in claim 32 and for at least the same reasons is patentable over Doi, Ichihara and Peck.

Conclusion

It is believed this amendment now has placed the application in condition for consideration and allowance. If necessary, the Commissioner is hereby authorized in this and

concurrent replies to charge payment (or credit any overpayment) to Deposit Account No. 50-0683 of Luce, Forward, Hamilton & Scripps.

Respectfully submitted,

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